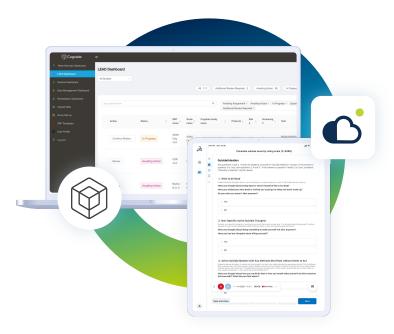


# Driving CNS Trial Success with Medidata & Cogstate

CNS trials present unique challenges due to the complex and varied nature of disorders in this therapeutic area. The need for precise assessments and data reliability is critical, yet it comes with significant operational burdens for sites and sponsors. To address these challenges, Medidata and Cogstate have joined forces, offering a deeply integrated, unified, patient and site-centric eCOA solution tailored for your CNS trial needs.

This partnership combines Medidata's industry-leading eCOA and site technology with Cogstate's CNS scientific and operational expertise to deliver a robust solution for end-to-end CNS study delivery. Together, Medidata and Cogstate deliver a streamlined assessment process, optimized endpoint data quality, and enhanced overall trial efficiency.



## Partnership Features

# 35 MEDIDATA

- Simplify the navigation of complex eCOA
  assessments with the Medidata App's intuitive
  navigation and progress indicator, enabling raters
  to skip ahead and quickly revisit any section of
  the form as needed.
- Offer raters flexible note-taking options including keyboard text, handwriting, or image capture of external notes - ensuring complete documentation of the assessment process.
- Leverage built-in audio recording with transcription, pause, and section markers, providing context for captured patient data and improving the overall reliability and quality of the assessment.
- Embed help and clinical guidance text in forms, supporting raters ability to perform and complete complex assessments with greater accuracy and consistency.



## Cogstate

- Qualify raters and minimize their burden with Cogstate's robust training programs, developed by clinical experts with first-hand knowledge of the scales and common rater errors.
- Ensure the highest endpoint data quality with Cogstate's strategic and risk-based central monitoring service, where clinical experts conduct targeted reviews of assessment data, providing raters with timely corrective feedback as needed.
- Detect subtle drug-related changes with Cogstate's scientifically validated library of digital cognitive tests, whose data has been used to support successful regulatory interactions and approvals.
- Enable sites to access experienced central raters, supporting assessment administration via telehealth, ensuring data quality, and reducing site and patient burden.



### Deep Integration Offers Comprehensive CNS Trial Solution

# 35 MEDIDATA X 🔯 Cogstate



#### **Automated Gated eCOA Access**

Enhance efficiency and compliance with automated gating access to eCOA forms on the Medidata App, integrated directly to Cogstate's learning management system. By linking these systems, only certified raters are granted access to conduct specific assessments.

#### Single Device Access to ClinRO and PerfO

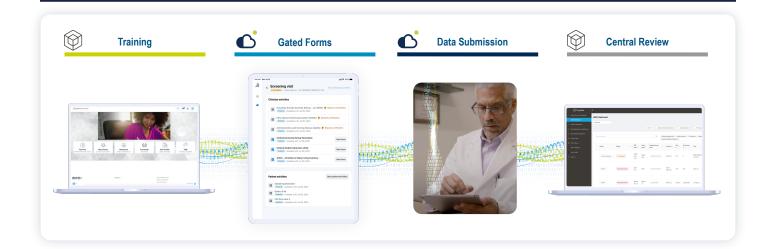
Simplify the cognitive assessment process by providing single device access for both ClinRO and PerfO assessments. This centralized access creates a seamless site and patient experience, while enabling a more holistic view of patient outcomes through a myriad of assessments.

#### **Streamlined Central Monitoring Workflow**

Ensure the highest standard of endpoint data quality with seamless integration between the Medidata App and Cogstate's central monitoring platform. Monitors are automatically queued for review upon data submission in the Medidata App, accelerating site feedback and improving study monitoring efficiency.

#### **eCOA Services with Scientific Support**

Elevate your CNS trials with Medidata and Cogstate's powerful partnership, combining end-to-end eCOA services with Cogstate's scientific and operational expertise. This comprehensive CNS support ensures a precise, patient and site-centric trial experience, positioning your CNS trials for success.



## The Medidata Advantage

Recognizing the inherent challenges in CNS trials, Medidata offers a transformative solution through our strategic partnership with Cogstate. Medidata's eCOA seamlessly integrates with Cogstate's robust rater training and central monitoring services, creating a unified, automated workflow tailored to the needs of patients, sites, and sponsors. Our eCOA solution, powered by Designer, empowers raters to confidently navigate and complete complex assessments, while integrating with Cogstate's platforms to ensure smooth workflows from eCOA access and data submission to central review. This streamlined approach not only enhances data quality and operational efficiency but also reduces the burden on raters, making Medidata and Cogstate your trusted partners for CNS trial success.